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10/578,968

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Matthias Rusing

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SUITE G

CHARLOTTE, NC 28226

EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

09/29/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/578,968

**Applicant(s)**

RUSING ET AL.

**Examiner**

Vera Afremova

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 19-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date 8/14/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of the Group I, claims 1-18, in the reply filed on 6/16/2009 is acknowledged.

Claims 19-25 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s), there being no allowable generic or linking claim. Election was made traverse in the reply filed on 6/16/2009.

Claims 1-18 are under examination in the instant office action.

***Claim Rejections - 35 USC § 112***

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the phrase "the total salt content being less than 3.5 g/L of total salts". It is unclear as claimed whether amount of sodium salts and chloride salts are less than 3.5 g/L or whether amount of all salts are less than 3.5 g/L. Claim 1 is confusing because it states that the medium is "without" salts of sodium and chloride but it also states that these salts are present in amount less than 3.5 g/L. Further, depending claims 7-9 indicate that some sodium and chloride salts are present in the medium.

Claim 3 appears to recite the use of calcium carbonate but it is unclear what medium or step of the claimed method might incorporate this salt.

Claim 6 appears to recite the use of sea water and /or "a low salt medium" but it is unclear what salts of sea water are intended and what medium or step of the claimed method

might incorporate the sea water or "low salt medium". It is unclear what is amount of salts in the sea water as intended.

Claims 10-13 recites the limitation "the low salt medium" in the method of claim 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 solely recites the use of "a fermentation medium".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,340,742 (Barclay).

Claims are directed to a method for cultivating microorganisms of the genus *Thraustochytriales*, wherein the microorganisms are cultivated in a fermentation medium with sodium salts and chloride salts being less than 3.5 g/L. Some claims are further directed to the use of microorganisms capable of producing more than 30 wt% oil per unit of weight of dry biomass, more than 10 % DHA per dry biomass or more than 5 % DPA per dry biomass. Some claims are further drawn to the absence or use of up to 3 g/L CaCO<sub>3</sub> in the medium. Some claims are further drawn to the use of the medium with total sodium and chloride salt fractions less than 1.75 g/L. Some claims are further drawn to the use of the medium with total chloride sodium content of the medium being is less than 250 mg/L. Some claims are further drawn to incorporation of various nutrients selected from glucose, yeast extract or corn steep liquor,

magnesium sulfate, calcium carbonate and potassium phosphate. Some claims are further drawn to incorporation salts of magnesium sulfate, calcium carbonate and/or potassium phosphate in amounts less than 3 g/L each. Some claims are further drawn to the medium pH 3-10, to the cultivation temperature between 10°C and 40°C, to the cultivation time for 1 to 10 days in the claimed method. Some claims are further drawn to the microorganisms belonging to the genus *Schizochytrium*, *Thraustochytrium* or *Ulkenia*.

US 5,340,742 (Barclay) teaches a method for cultivating microorganisms belonging to *Thraustochytriales* including representatives of the genus of *Schizochytrium* as intended for production of oils, DHA and/or DPA, wherein the microorganisms are cultivated in a fermentation medium of low salinity and/or low amounts sodium salts and chloride salts, for example: see entire document including col. 23-24. The fermentation medium does not contain chloride and the amount of sodium salts is below 3.5 g/L (table 8); the microorganism is capable of producing more than 40% of total lipids (more than 30 wt% oil per unit of weight of dry biomass) and about 10% of omega-3 oils or more than 10 % DHA per dry biomass or more than 5 % DPA per dry biomass. The cited patent US 5,340,742 (Barclay) teaches that the fermentation medium contains sodium carbonate less than 3 g/L ( col. 24, line 6). In the cited method the total sodium and/or chloride salt fractions in the medium salts are less than 1.75 g/L as required by the claimed method, for example: see table 10, wherein “minimal chloride” medium contains about 0.76 g/L of sodium ion as weight fraction in 2.37 g/L of sodium sulfate. In the cited method the medium total chloride sodium content is less than 250 mg/L (table 10). In the cited method the medium contains glucose, yeast extract, magnesium sulfate, calcium carbonate and potassium phosphate (col. 24, lines 5-8) and corn steep liquor is also used as a source of nitrogen (table 6).

The amounts of magnesium sulfate, calcium carbonate and potassium phosphate are less than 3 g/L each (col. 24, lines 5-8). The cited patent US 5,340,742 (Barclay) teaches the use of medium pH 3-10, cultivation temperature between 10°C and 40°C and cultivation time for 1 to 10 days in the method for cultivating microorganisms belonging to *Thraustochytriales* or *Schizochytrium* as intended for production of oils, DHA and/or DPA.

Thus, the cited patent US 5,340,742 (Barclay) anticipates the claimed invention.

Claims 1-7 and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,509,178 (Tanaka et al.).

Claims are directed to a method for cultivating microorganisms of the genus *Thraustochytriales*, wherein the microorganisms are cultivated in a fermentation medium with sodium salts and chloride salts being less than 3.5 g/L. Some claims are further directed to the use of microorganisms capable of producing more than 30 wt% oil per unit of weight of dry biomass, more than 10 % DHA per dry biomass or more than 5 % DPA per dry biomass. Some claims are further drawn to the absence or use of up to 3 g/L CaCO<sub>3</sub> in the medium. Some claims are further drawn to the use of the medium with total sodium and chloride salt fractions less than 1.75 g/L. Some claims are further drawn to incorporation of various nutrients including glucose, yeast extract or corn steep liquor, magnesium sulfate, calcium carbonate and potassium phosphate in the medium. Some claims are further drawn to incorporation salts of magnesium sulfate, calcium carbonate and/or potassium phosphate in amounts less than 3 g/L each. Some claims are further drawn to the medium pH 3-10, to the cultivation temperature between 10°C and 40°C, to the cultivation time for 1 to 10 days in the claimed method. Some claims are further

drawn to the microorganisms belonging to the genus *Schizochytrium*, *Thraustochytrium* or *Ulkenia*. Some claims are further drawn to the microorganisms belonging to *Ulkenia* sp. SAM 2179.

US 6,509,178 (Tanaka et al.) teaches a method for cultivating *Thraustochytriales* microorganisms including *Ulkenia* sp. SAM 2179 as intended for production of oils, DHA and/or DPA (see entire document) wherein the microorganisms are cultivated in a fermentation medium with low amounts of sodium salts and of chloride salts which are less than 3.5 g/L or which are 2.6 g/L (col. 9, lines 10-25). The microorganism is capable of producing more than 30 wt% oil per unit of weight of dry biomass, more than 10 % DHA per dry biomass or more than 5 % DPA per dry biomass (table 3, for example). The medium does not contain calcium carbonate (example 2) and that falls in the claimed range 0-3 g/L. The total sodium and chloride ions salt weight fractions are less than 1.75 g/L or about 1.47 g/L (col. 9, lines 14-16). The medium contains glucose, corn steep liquor, salts of magnesium and potassium phosphate (example 2) with amount salts being about or less than 3 g/L each (example 2). The cited patent US 6,509,178 (Tanaka et al) teaches the use of medium pH 3-10, cultivation temperature between 10°C and 40°C and cultivation time for 1 to 10 days in the method for cultivating microorganisms belonging to *Thraustochytriales* or *Ulkenia* sp. SAM 2179 as intended for production of oils, DHA and/or DPA.

Thus, the cited patent US 6,509,178 (Tanaka et al) anticipates the claimed invention.

Claims 1-16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokochi et al. ("Optimization of docosahexaenoic acid production by *Schizochytrium limacinum* SR21". Appl. Microbiol. Biotechnol. 1998, vol.49, pages 72-76).

Claims are directed to a method for cultivating microorganisms of the genus *Thraustochytriales*, wherein the microorganisms are cultivated in a fermentation medium with sodium salts and chloride salts being less than 3.5 g/L. Some claims are further directed to the use of microorganisms capable of producing more than 30 wt% oil per unit of weight of dry biomass, more than 10 % DHA per dry biomass or more than 5 % DPA per dry biomass. Some claims are further drawn to the absence or use of up to 3 g/L CaCO<sub>3</sub> in the medium. Some claims are further drawn to the use of the medium with total sodium and chloride salt fractions less than 1.75 g/L. Some claims are further drawn to the use of the medium with total sodium content of the medium being is less than 150 mg/L. Some claims are further drawn to the use of the medium with total chloride sodium content of the medium being is less than 250 mg/L. Some claims are further drawn to incorporation of various nutrients including glucose, yeast extract, corn steep liquor, magnesium sulfate, calcium carbonate and/or potassium phosphate in the medium. Some claims are further drawn to incorporation salts of magnesium sulfate, calcium carbonate and/or potassium phosphate in amounts less than 3 g/L each. Some claims are further drawn to the medium pH 3-10, to the cultivation temperature between 10°C and 40°C, to the cultivation time for 1 to 10 days in the claimed method. Some claims are further drawn to the microorganisms belonging to the genus *Schizochytrium*, *Thraustochytrium* or *Ulkenia*. Some claims are further drawn to the microorganisms belonging to *Schizochytrium* sp. SR 21.



The cited reference by Yokochi et al. teaches a method for cultivating microorganisms of *Thraustochytriales* including *Schizochytrium* sp. SR 21 as intended for production of oils, DHA and/or DPA (see entire document), wherein the microorganisms are cultivated in a fermentation medium without salts (figure 1a) and, thus, without sodium and/or chloride salts or with amounts being less than 3.5 g/L or less than 1.75 g/L, 250 mg/L or 150 mg/L within the broadest meaning of the claims. The microorganism is capable of producing oils, DHA and DPA in amounts more than 30 wt% oil per unit of weight of dry biomass, more than 10 % DHA per dry biomass or more than 5 % DPA per dry biomass depending on the choice of nitrogen source and/or ratio of C/N (table 2 or page 76, col. 1, par. 3). The cited reference teaches incorporation of various nutrients including glucose, yeast extract, corn steep liquor, magnesium sulfate and/or potassium phosphate in the fermentation medium, the medium pH 3-10, the cultivation temperature between 10°C and 40°C and the cultivation time for 1 to 10 days in the method for cultivating microorganisms of *Thraustochytriales* including *Schizochytrium* sp. SR 21.

Thus, the cited reference by Yokochi et al. anticipates the claimed invention.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,340,742 (Barclay), US 6,509,178 (Tanaka et al.), Yokochi et al. ("Optimization of docosahexaenoic acid production by *Schizochytrium limacinum* SR21". Appl. Microbiol.

Biotechnol. 1998, vol.49, pages 72-76) and Fan et al. ("Physiological studies of subtropical mangrove thraustochytrids". Botanica Marina, 2002, col. 45, pages 50-57).

Claims are directed to a method for cultivating microorganisms of the genus *Thraustochytriales*, wherein the microorganisms are cultivated in a fermentation medium with sodium salts and chloride salts being less than 3.5 g/L. Some claims are further directed to the use of microorganisms capable of producing more than 30 wt% oil per unit of weight of dry biomass, more than 10 % DHA per dry biomass or more than 5 % DPA per dry biomass. Some claims are further drawn to the absence or use of up to 3 g/L  $\text{CaCO}_3$  in the medium. Some claims are further drawn to the use of the medium with total sodium and chloride salt fractions less than 1.75 g/L. Some claims are further drawn to the use of the medium with total sodium content of the medium being is less than 150 mg/L. Some claims are further drawn to the use of the medium with total chloride sodium content of the medium being is less than 250 mg/L. Some claims are further drawn to incorporation of various nutrients including glucose, yeast extract, corn steep liquor, magnesium sulfate, calcium carbonate and/or potassium phosphate in the medium. Some claims are further drawn to incorporation salts of magnesium sulfate, calcium carbonate and/or potassium phosphate in amounts less than 3 g/L each. Some claims are further drawn to the medium pH 3-10, to the cultivation temperature between 10°C and 40°C, to the cultivation time for 1 to 10 days in the claimed method. Some claims are further drawn to the microorganisms belonging to the genus *Schizochytrium*, *Thraustochytrium* or *Ulkenia*. Some claims are further drawn to the microorganisms belonging to *Ulkenia* sp. SAM 2179 or *Schizochytrium* sp. SR 21.

The cited patents US 5,340,742 (Barclay) and US 6,509,178 (Tanaka et al.) and the cited reference by Yokochi et al. are relied upon as explained above for the disclosure of method for cultivating microorganisms belonging to *Thraustochytriales* including *Ulkenia* sp. SAM 2179 and *Schizochytrium* sp. SR 21 as intended for production of oils, DHA and/or DPA.

In the methods of the cited patents US 5,340,742 (Barclay) and US 6,509,178 (Tanaka et al.) the microorganisms are cultivated in fermentation media with low amounts of sodium salts and chloride salts or with total amounts being less than 3.5 g/L. In the method of the cited reference by Yokochi et al. the microorganisms are cultivated in fermentation media in the absence of salts. The cited reference by Yokochi et al. also teaches that optimization of lipid production by representatives of *Thraustochytriales* including strain *Schizochytrium* sp. SR 21 depends on the choice of nitrogen source and/or ratio of C/N in the fermentation media (table 2 or page 76, col. 1, par. 3).

In addition, the reference by Fan et al. is relied upon to demonstrate that various representatives of *Thraustochytriales* including *Schizochytrium*, *Thraustochytrium* and *Ulkenia* are successfully grown at zero salinity (fig. 2) and/or in the absence of sodium salts and chloride salts

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice method of culturing representatives of *Thraustochytriales* in low salinity media with a reasonable expectation of success in producing lipid containing biomass because it has been known that various representatives of *Thraustochytriales* including *Schizochytrium*, *Thraustochytrium* and *Ulkenia* are successfully grown at zero salinity and/or in low salinity media as adequately demonstrated by the cited

references combined. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

September 25, 2009

/Vera Afremova/

Primary Examiner, Art Unit 1657